REMARKS

In the Office Action dated May 23, 2008, claims 1-20 were said to be pending in the application. Claims 9-11 were objected to as being directed to a stent and a balloon. Claims 12 and 13 were objected to under 35 U.S.C. § 112. Claims 1-8 were rejected under 35 U.S.C. § 102(b) as being anticipated by Smith (U.S. Patent No. 6,364,904). Claims 9-11 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,375,660 to Fischell et al. (Fischell). Claims 12 and 14-19 were rejected under 35 U.S.C. § 102(b) as being anticipated by EP 12 54 645 to Houston et al. (Houston). Claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston. Claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Houston in view of U.S. Patent No. 5,733,327 to Igaki et al. (Igaki). For the reasons outlined in detail below, it is respectfully submitted that the pending claims are in patentable condition over the art of record.

Claim Objections to Claims 9-11

Claims 9 and 10 have been rewritten to now recite a stent in combination with a balloon. Therefore, it is believed that claims 9 and 10 should no longer be considered objectionable. Claim 11 has been cancelled without prejudice.

35 U.S.C. § 112 Rejections

Claims 12 and 13 have been amended to overcome the § 112 rejection raised thereagainst. It is therefore believed that the § 112 rejection is now moot.

Independent Claim 12 and its Dependent Claims 13-20, 1, 3-6, 9, 10 and 21-23

Independent Claim 12 was rejected as being anticipated by Houston. This

rejection is set forth in paragraph 17 on pages 6 and 7 of the Office Action. Applicant notes that claim 12 is the sole independent claim currently pending in the application. Claim 12 has been amended to recite a stent for insertion in a fluid conduit of a human or animal body when the stent is in a collapsed condition and for expansion to an expanded condition. In the expanded condition, the stent caused the fluid conduit to have a flow lumen having a center line which follows substantially a helical path. The stent, when expanded ex vivo, has a helix angle less than or equal to 65° and a helical center line having an amplitude less than or equal to 0.7 of the internal diameter of the stent.

It was stated in the Office Action that Houston discloses a tubing or stent (Figure 3) for insertion in a fluid conduit of the human or animal body (column 3, lines 13-14) when the stent is in a collapsed condition and for expansion to an expanded position (column 3, lines 46-51), wherein in the expanded condition, the stent causes the fluid conduit to have a flow lumen having a center line which follows a substantially helical path, the helical center line having a helix angle less than or equal to 65° (column 6, lines 28-31) and an amplitude less than ½ of the internal diameter of the flow lumen (Figure 3).

Figure 3 of Houston is described in column 5 at paragraph 33. It is there stated that "as seen in Figure 3, a non-circular section tube 11 can have a twist." Applicants first note that the disclosure in Houston is to a tube and not to a stent, as recited in pending claim 12. Further, it appears from Figure 3 that the non-circular section of the tube is an oval or an ellipse and that this oval has been twisted about a horizontal axis or a straight axis. Therefore, Figure 3 of Houston fails to disclose a) a stent and b) a

stent which has a center line that is helical, as is recited in claim 12.

In order to demonstrate that Figure 3 of Houston discloses only a horizontal center line or straight center line rather than a helical center line, applicants submit herewith two drawings.

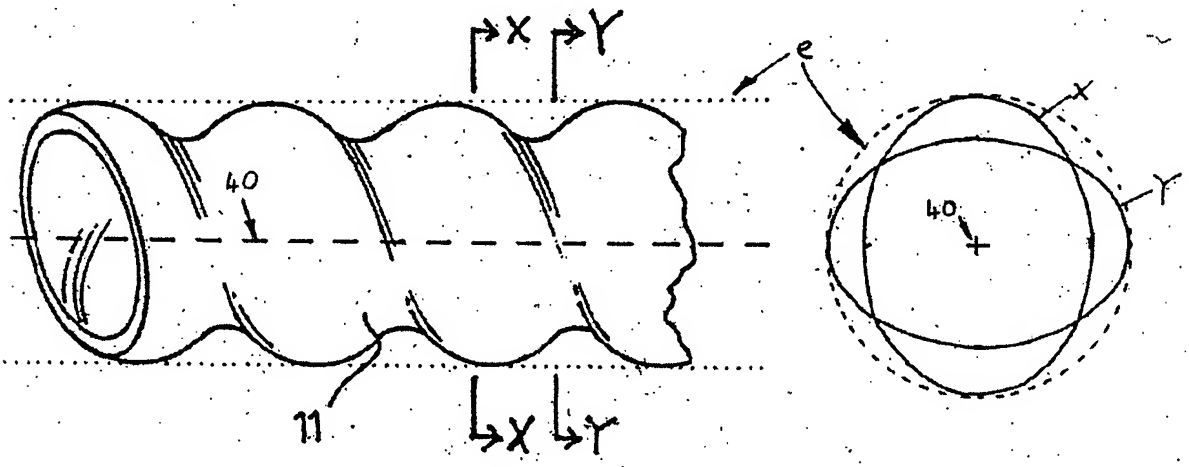

Fig. A

Fig. B

The first of these, Figure A, is identical to Figure 3 shown in Houston. The second of these, Figure B, shows two cross sectional slices taken along lines XX and YY of Figure A, which lie perpendicular to the axis 40 of the Houston tube 11. In the case of the tube with an elliptical cross section, these slices will also appear to be elliptical. Moving along the axis of the envelope, it can be seen that the cross sectional shapes (ellipses) do not change other than be rotating around the central axis. In other words, as we move along the axis, the cross section is twisted about the axis. This is stated in paragraph 33 of Houston as follows: "a non-circular section tube 11 can have a twist, and may also have internal ridging and/or grooving." In Figures A and B, applicants have attempted to mark the cross sections X and Y such that they are rotated by a

quarter turn relative to one another. It can be seen that the elliptical cross section has been rotated by 90° between the cross sections X and Y. The centroids of both elliptical cross sections, however, stay on the axis 40. Therefore, Figure 3 of Houston fails to disclose a) a stent and b) a stent having a helical center line. Instead, Houston merely shows a) a tube and b) a tube having a straight center line.

While paragraph 33 does discuss a circular section tube as well "bent into a corkscrew shape" (as does paragraph 11), applicants again note that the disclosures in Houston refer to tubes and not to stents. It is clear from paragraph 27 of Houston that the term "tubing" discussed in Houston refers to "all types of conduit which transport or contain liquid or gaseous fluid...". However, the proposals in Houston concerning corkscrew shaped tubing does not provide any disclosure of a stent having a corkscrew shape. While stents are disclosed in Figures 9-12 of Houston and in paragraphs 39 and 22, the spiral flow inducing property is imparted in the stents by the use of radially inwardly projecting vanes such as at 104 shown in Figures 10 and 12. This embodiment of Houston has a plurality of vane members 104 equally spaced about the circumference of the stent. The vane members are said to be arranged at an angle to the longitudinal direction of the stent to provide the required "internal spiral formation." It should be apparent that in such a stent, the center line is straight and not helical. That is because the center line is at the center of the cylindrical stent 101 both where the vane members 104 are present and where they are not. The presence and absence of the vane members is evident from Figures 9 and 11 of Houston. It can there be seen that the vanes 104 are only present in a limited section of the stent 101.

In sum, where stents are described in Houston, they are cylindrical. An internal

spiral formation consisting of vane members 104 is taught by Houston to provide a helical flow inducing effect. But, the stents of Houston, as with the tubes of Houston, do not have a helical center line, as is recited in pending claim 12.

Moreover, applicants submit that the corkscrew configuration of Houston requires a large amplitude and does not fulfill the requirement for the amplitude of the stent ex vivo to be less than or equal to 0.7 of the internal diameter of the flow lumen. In a corkscrew, the coils are wound around a straight core, whether of air or of solid material. Therefore, the amplitude of the helix will be greater than 0.7 times the internal diameter of the flow lumen. This is discussed in the instant specification on page 9, line 37 to page 10, line 10. It is there noted that:

> "It is usual for the helix of a corkscrew to have a clear gap down the middle...(and, thus,) the amplitude of the helix would be greater than one half of the internal diameter of the tubing and there would be no "line of sight" along the inside of the tubing."

As noted in that paragraph, such a design is relatively bulky and unsuitable for certain applications.

Therefore, even if someone were to interpret Houston as disclosing corkscrew shaped stents (which is incorrect since the stent disclosures in Houston are to vanes projecting into an otherwise cylindrical stent body having a straight center line, instead of a helical center line) there would still be no disclosure of a helical stent with a low helical amplitude geometry as recited in claim 12, i.e., a relative amplitude less than or equal to 0.7. In this connection, the basis for claiming the stent ex vivo as having a maximum relative amplitude of 0.7 can be found in the instant specification on page 11,

line 37 to page 12, line 7. It is there stated that:

> "The stent may be designed to have a relative amplitude greater than 0.5 (e.g., 0.6 or 0.7), but so that in use, a relative amplitude of the flow lumen is equal to or less than 0.5. In certain preferred arrangements, however, the relative amplitude of the expanded stent ex vivo is less than or equal to 0.5."

It is because the stent in claim 12 is defined ex vivo that claim 12 now recites that the maximum relative amplitude (that is the amplitude of the helical center line divided by the internal diameter of the flow lumen) is less than or equal to 0.7. Applicants respectfully submit that claim 12 as presented herein in neither anticipated by nor rendered obvious by Houston. In this connection, applicants refer to page 3 of the instant specification. The Houston reference is there discussed in detail in lines 3-20.

Mentioned is "a stent in the form of a mesh cylinder, with vane members attached to the inside of the cylinder so as to project into the fluid passage and guide the flow." This is disadvantageous because the vanes may obstruct flow and increase flow resistance. This is especially true if there is any build-up of material on the vanes. In addition, the specification goes on to point out that the use of vanes may not reliably induce swirl flow across the entire cross section of flow. In other words, there may be a tendency for flow nearer the center of the tube to follow a linear path rather than a helical path. Also, the provision of vanes over a relatively short length of flow, as in Houston, is likely to create only a temporary alteration of flow characteristics, with the flow reverting to a normal pattern at a distance downstream of the vanes.

It is respectfully submitted that claim 12 as presented herein is in condition for

allowance over the applied Houston reference, as well as the remainder of the art of record.

Claim 13 has been amended to recite that the amplitude of the helical center line of the stent divided by the internal diameter of the stent is at least 0.05. Dependent claims 13-20, which merely further patentably define the detailed subject matter of their parent claim are also believed to be in condition for allowance over not just Houston, but the remainder of the art of record, including Igaki, which was applied against claim 20.

Applicant has amended previous independent claim 1 to now be dependent on claim 12. Moreover, claim 1 has received a clarifying amendment which makes clear the fact that the helical portion "resists extension more than the portions of the stent adjacent to the helical portion." The basis for this clarifying amendment can be found in the instant specification on page 7, lines 1-4. Dependent claims 3 and 4 have been made now dependent on claim 12. Claim 4 has also been amended to recite that the helical portion comprises structural members having bent portions which resist unbending during expansion of the stent more than a portion of the stent adjacent to the helical portion. Claims 5 and 6 have also been amended to now be dependent on claim 12.

Claim 9 has been redrafted in dependent form to now depend from claim 12. This claim has also received clarifying amendment to make it clearer that the balloon expandable stent is now claimed in combination with a balloon for expanding the stent. Basis for this amendment can be found in the instant specification on page 9, at lines 13-16. There, it is made clear that the balloon is removed after insertion of the stent, thereby implying that the balloon and stent are used in combination, rather than the

stent comprising the balloon. Claim 9 has also been amended to better define the helical portion. Basis for this amendment can be found in the instant specification on page 9 at lines 26-28.

Applicants take this opportunity to submit new dependent claims 21-23. Claim 21 recites that the amplitude of the helical center line of the stent, divided by the internal diameter of the stent is at least 0.1. Support for claim 21 can be found in the instant specification on page 11 at line 20.

Applicants also submit new dependent claim 22. This claim recites that the stent of claim 1 undergoes at least one turn of the helix. Basis for this claim can be found on page 13 of the instant specification at lines 25-31. New claim 22 is also similar to original claims 7 and 11. Therefore, no new matter is being presented.

Finally, applicants submit new claim 23. This claim recites that the helical portion has the same number of turns, both when the stent is collapsed and when it is expanded. This recitation is supported by originally filed claim 8, which recites that the stent expands from the collapsed condition to the expanded condition without substantial twisting.

In view of the foregoing, it is respectfully submitted that the pending claims patentably define over Houston, as well as the rest of the art of record.

Summary

In view of the foregoing amendments and comments, applicants respectfully submit that all of the pending claims are now in condition for allowance over not only Houston, but the remainder of the art of record. Such allowance is earnestly solicited.

Respectfully submitted,

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